RAJYA SABHA

Friday, the 31*st July,* 2009/9 *Sravana,* 1931 *(Saka)*

The House met at eleven of the clock,
MR. CHAIRMAN in the Chair.

ORAL ANSWERS TO QUESTIONS

Regulation of Human Genetic Research

*401. SHRI P. RAJEEVE: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether there are any legislations to regulate Human Genetic Research;

(b) if so, what is the institutional mechanism to regulate the same;

(c) whether there are any provisions for protection of medical data derived from patients; and

(d) whether there is any provision for protection of genetic material taken from human body?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) There are no specific legislations to regulate Human Genetic Research, although the Pre-conception and Pre-natal Diagnostic Techniques (PC&PNDT) (Regulation and Prevention of Misuse) Act covers some aspects of Human Genetic Research. However, a bill to regulate Bio-medical research on human subjects is being finalized.

(c) and (d) There are no direct provisions for protection of medical data and genetic material. However, guidelines have been issued by the Ministry, for exchange of Biological Material in 1997 for protection of genetic material in case the biological material is to be transferred to another country.

SHRI P. RAJEEVE: Sir, the answer shows the pathetic condition, in India, regarding this genetic research. Twelve years have passed since the U.S. Declaration on Human Genome and Human Rights. And in 2003, the Hyderabad Convention directed the Government to make an enactment as the Genetic Privacy Act. But nothing has happened. Some reports are there that the MNCs have misused this genetic research for their purpose and some countries have used this for their vested interest. Sir, I would like to know, through you, Sir, from the hon. Minister whether the existing provisions are sufficient to prevent the misuse and commercialisation of genetic samples taken as a research subject.

SHRI DINESH TRIVEDI: No, Sir. The present Act or the guidelines are not, really, sufficient, and that is the reason why a new Act is coming in front of the Parliament, which is known as the Biomedical Research on Human Participants (Promotion and Regulation) Bill. At the moment, it is in wide circulation, and to prevent such misuse which the hon. Member has, rightly, pointed out, because at the moment, it does not come under any particular regulation as such; it only comes under the guidelines. Once this Bill is passed as an Act, I am sure, this will cover the entire gamut of genetic research.

MR. CHAIRMAN: Second supplementary.

SHRI P. RAJEEV: Sir, the Minister has mentioned no reason for an unjustifiable delay in making this enactment. This is, actually, not a right action to the country and to the people. Sir, there is some Ethics Committee like the Animal Ethics Committee, at the institutional level, for monitoring the research using animals as a subject, and also, some Bio Safety Committee. I would like to know, through you, Sir, from the hon. Minister whether the Government has any plans to constitute a Genetic Safety Committee to monitor genetic research at the institutional level.

MR. CHAIRMAN: Thank you.

SHRI DINESH TRIVEDI: Sir, this new Bill, about which I just mentioned, covers the entire gamut. It also envisages a regulatory body. At the moment, it is at the nascent stage, establishment of Biomedical Research Authority, under which the Ethics Committee also would come. At the moment, the Ethics Committee is just in the form of guidelines. So, I totally agree that as in terms of the delay, Sir, if you permit me, I can answer that also.

SHRI P. RAJEEV: That is good further. ...*(Interruptions)*...

MR. CHAIRMAN: I think you have answered the question.

SHRI DINESH TRIVEDI: Thank you, Sir.

MR. CHAIRMAN: Thank you. Shri Shantaram Laxman Naik.

SHRI SHANTARAM LAXMAN NAIK: Sir, if Mahatma Gandhi can be made to reborn with all his genes, his quality, his honesty, his dedication, thoughts and simplicity, this will be a research and law worth having it. All of us... ...*(Interruptions)*...

MR. CHAIRMAN: What is the question?

SHRI SHANTARAM LAXMAN NAIK: All of us who are going astray need guidance, maybe, through Mahatma Gandhi in a clone form. Any response from you?

SHRI DINESH TRIVEDI: I have no doubt; the entire population of this world would like to become Mahatma Gandhi. But till such time, we only have to adopt his principles, which we all are trying to do, Sir.

DR. C.P. THAKUR: Sir, actually the genetic research is in its infancy stage and, therefore, there are not many regulations for its preservation. Now, the Health Ministry has converted one

unit of the Indian Council of Medical Research into a department headed by an officer of the Secretary level. They can now push for genetic research in India also. When the genome research was going on, India did not participate. That is the hindrance. I would like to know from the Minister what he proposes to do in the coming years to give a boost to genetic research.

SHRI DINESH TRIVEDI: Sir, the hon. Member is a doctor and he had an illustrious innings in this particular Ministry. We have started a new department which is known as "Department of Health Research". Earlier many researches were taking place in this country. India is very proud, as far as knowledge is concerned. The entire world looks at India because this is a country of knowledge. But, unfortunately, that knowledge has not been channelised. Dr. Sahib was the one who had created the base when he was the Health Minister. Genome is something in which we have experts in this country. To answer this question, we already have a new department since September, 2007 and this department will channelise all the research which is taking place so that all the results can be coordinated.

SHRIMATI VASANTHI STANLEY: Sir, it is apprehended that genetic research seeds, which have been distributed with or without the knowledge of the Government, will affect the genome type of the Indian population. Is there any institutional mechanism to regulate the same?

SHRI DINESH TRIVEDI: Sir, at the moment, there is no mechanism; there are only guidelines. Whenever we send some samples abroad for scientific study or diagnosis, it comes under these guidelines for exchange of human biological material for biological research purpose of 1997. But, again, I repeat that once we pass this particular Bill into an Act, your concern will be covered by that.

Railway projects in Rajasthan

*402. DR. GYAN PRAKASH PILANIA:††
SHRI LALIT KISHORE CHATURVEDI:

Will the Minister of RAILWAYS be pleased to state:

(a) whether Government is aware that certain Railway projects, which were announced 10 years, 15 years and 20 years ago, are still incomplete in Rajasthan;

(b) if so, the details thereof;

(c) the extra amount spent by the Railways, project-wise, besides the cost of the original project due to the above delay; and

(d) by when these delayed projects are likely to be completed?

THE MINISTER OF STATE IN THE MINISTRY OF RAILWAYS (SHRI E. AHAMMED): (a) to (d) A statement is laid on the Table of the House.

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††The question was actually asked on the floor of the House by Dr. Gyan Prakash Pilania.